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IN THE SUPREME COURT

OF THE UNITED STATES

OCTOBER TERM, 1991

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DUANE L. ISAACS,

Petitioner,

vs.

UNITED STATES OF AMERICA,

Respondent,

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# PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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## QUESTIONS PRESENTED

1. Is it irrational and therefore a violation of Equal Protection if the Medicare program reimburses patients for foot care essential to **treat** serious complications resulting from various systemic diseases, most notably diabetes mellitus or peripheral vascular disease (PVD), but denies reimbursement, per 42 U.S.C. 1395y(a)(13)(C) and Sections 2323(C)and 4120.1 of The Part B Medicare Carriers' Manual, for the same foot care where it is essential to **prevent** those conditions' serious complications where that denial may result in loss of limb or death?

2. Does the petitioner-physician have standing to vindicate his and his Part B Medicare patients' Due

Process/Equal Protection rights, where continuing loss of income and interference with his practice result from Medicare's denial of reimbursement for foot care advocated as essential to prevent serious, inevitable complications of systemic disease, and where that denial causes those patients to decline such service?

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## OPINIONS BELOW

The unpublished memorandum decision of the Court of Appeals for the Ninth Circuit, of which this petition seeks review via a writ of certiorari, is reprinted in the appendix hereto, p.1. The district court's unreported order is reprinted in the appendix hereto, p. 9. Its order subsequent to petitioner's request for reconsideration was specifically excluded from the Ninth Circuit's consideration (see footnote 1 of appellate decision, appendix at p. 5) and is not appended.

## JURISDICTION

I began this case pro se in the Phoenix, Arizona district court, invoking jurisdiction under 28 U.S.C. 1331, 2201, and 2202. That court denied my motion for summary judgement on the basis that I lacked standing to vindicate my patients' interests

as a means of vindicating my own and that my claims lacked merit. The United State's cross-motion for summary judgement was granted. The Court of Appeals for the Ninth Circuit, after de novo consideration of my appeal under 28 U.S.C. 1291, affirmed the district court's decision on 4 June 1991.. On 16 August 1991, my petition for rehearing was denied (Appendix, p. 23). This petition for a writ of certiorari is timely under this court's Rule 13.4. Its jurisdiction is invoked under 28 U.S.C. 1254.

STATUTE AND REGULATIONS INVOLVED

42 U.S.C. 1395y(a)(13)(C) and Sections 2323(C) and 4120.1 of The Part B Medicare Carriers' Manual. Full text of each is appended at p. 33; p. 25; p. 27, respectively.

STATEMENT OF THE CASE

I'm a podiatrist, licensed in

Arizona to diagnose and treat, by medical and surgical means, illness and injury of the human foot. The already high percentage of Medicare-insured elderly with severe diabetes and/or almost no circulation in feet and legs (PVD) increases yearly in my podiatry practice. Many are referred by their medical doctors since only podiatrists perform certain foot care these patients must have. If they don't receive it, i.e., professional debridement (cutting, removal) of corns, callouses, and nails at appropriate intervals based on my assessment of each patient's rapidly-changeable conditions, they all quickly and inevitably develop open, infected sores (ulcers) commonly progressing to gangrene requiring amputation of feet and legs. Death may ensue. Medicare recognizes that my patients can't afford such

preventive foot care (PFC) without its help. If I document on the Medicare claim form certain specific clinical findings which support my professional judgement that the severity of the patient's systemic disease renders PFC essential to avoid those complications, Medicare **may** pay about $20 of my $25 charge for their PFC every two months **only if** the clerical claims-processors find that the claim meets Medicare's narrow, stringent guidelines for PFC coverage under the challenged policy directive. Under optimal circumstances, this frequency suffices. Unfortunately, continuing optimal circumstances is not the rule for these patients. Changes in systemic disease and intrinsic foot pathology often necessitate more frequent treatment to prevent complications, either on a temporary or permanent basis. The

paradox is, when I identically document that a given patient now needs more frequent PFC to prevent this hazard, Medicare **always automatically** denies it, per a law that excludes from coverage "routine foot care (including the cutting or removal of corns or callouses, the trimming of nails and other routine hygienic care)," 42 U.S.C. 1395y(a)(13)(C). The almost invariable result is that my patients decline PFC advocated by me and I end up treating complications that should never have occurred. Conversely, after the patient consequently suffers these devastating complications, my weekly service and all other treatment of these complications (remedial care) automatically is covered ad infinitum unless excluded as "not reasonable and necessary for the diagnosis or treatment of illness," per 42 U.S.C. 1395y(a)(1). Medicare rarely questions

the medical necessity of such remedial care, owing to the wide range of medical circumstances and services which correlate within this definition.

Medicare law prohibits me (by threat of program exclusion and severe monetary penalties) from collecting from patients for either PFC or remedial care denied by the program as "not reasonable and necessary," unless I can show either that I informed the patient that Medicare would deny reimbursement on this basis, or that I could not have known that denial would occur. 42 U.S.C. 1395u(1), appended at p. 34, is representative of this prohibition. Owing to the wide range of medical circumstances and services which correlate as reasonable and necessary, I need not be consequently concerned about remedial care. However, because of Medicare's stringent PFC guidelines,

I cannot use lack of constructive knowledge as a defense for PFC denials. In order to ensure that I do not perform the service free or incur sanctions, I must inform all systemic disease patients that all PFC not conforming will be considered "unnecessary" and denied, even though this is contrary to my professional judgement. When I do so, they decline the service, either as unaffordable or because of doubts about my judgement.

Medicare's different payment policies for PFC versus remedial care are established by Section 4120.1 of The Part B Medicare Carriers Manual (The Manual), which directs nationwide the coverage determinations made by government-contracted private insurance companies which process Medicare claims for physicians' services. This section directs the use of The Manual's Section

2323(C), implementing 42 U.S.C. 1395y(a)(13)(C), to exclude systemic disease PFC as "routine foot care." Its paragraph 3 delineates the narrow circumstances for PFC coverage.

The challenge here is that, either facially or as applied, 42 U.S.C. 1395y(a)(13)(C) and The Manual's Sections 4120 and 2323(C) violate my and my systemic disease Medicare patients' Due Process/Equal Protection rights (see relevant sections of my Complaint and Memorandum in Support of Summary Judgement, appended, pp. 24-25). There is no rationale, medical or otherwise, to this policy of virtually unquestioned, unlimited program payment for all remedial care, but automatic denial of reimbursement for care which would prevent these horrible consequences. If these were otherwise healthy patients at little or no risk from failure to obtain

PFC, denying it as "routine foot care" would make sense, but Medicare's recognition that serious complications, including amputations, inevitably follow inadequate PFC for systemic disease patients is inherent in its policy of paying for some PFC. There is no logic in admitting the efficacy of "some" prevention, but not all that is reasonable and necessary to achieve this aim. All doctors involved in the multi-specialty management of these patients' systemic disease concur that PFC obviates such loss. It is thus reasonable and necessary to treat serious systemic illness, satisfying Medicare's reimbursability criterion applicable to all other medical service per 42 U.S.C. 1395y(a)(1). This is evident from its inclusion in 42 U.S.195u(1), which applies **only** to service denied as not reasonable and necessary.

The same discrimination applies whether PFC is advocated and performed by a podiatrist or a doctor of medicine or osteopathy. Medicare trusts my professional acumen to certify the necessity of all remedial care, but not PFC, despite that I am state-licensed to diagnose the need for, and to perform, all service relevant here, satisfying Medicare's reimbursability criterion applicable to service performed by all types of physicians. Debridement is the medical service involved in both PFC and treatment of ulcers (removal of non-viable tissue which impedes healing is an essential part of the latter). It's the same patient, only at different times. The financial cost of remedial care to both Medicare and the patient is greater than PFC's. Treatment of even the simplest inevitable complication, full-thickness

skin ulcers, involves weekly debridement for which doctors' charges are $400 monthly, with hospitalization frequently required for concomitant infection treatment. Medicare's remedial care costs also include those for rehabilitation, prosthetic limbs, and treatment of inevitable future illness resulting from amputation. At the same time, the patient's burden is increased because of liability for deductibles and the 20% co-insurance not paid by Medicare for the higher cost of remedial care or unreimbursed costs of PFC.

It's no help that carriers' initial PFC denials may be appealed, particularly when the patient needs the service every 2-3 weeks. The available multi-stage comprehensive appeal procedure may be adequate for service where time is not of the essence, but it is inherently too

slow to prevent my patients from declining PFC needed to prevent imminent complications. The $100 minimum for initiating appeals requires 5 PFC denials. If successful, reversals are service-date specific. Other past, or future, more-frequent-than-allowed PFC will still be denied for a given patient. In 22 years of Medicare practice, in which I've participated on behalf of my systemic disease patients in hundreds of appeals involving PFC denials, I've **never** seen reversal of an initial PFC denial in time to prevent complications. Consequently, few podiatrists whom I know even bother submitting PFC claims for more-frequent-than-allowed treatment, much less appealing denials. It's easier and more profitable simply to await onset of complications.

The lower courts misapprehended

my claims and arguments, probably because I attempted to emphasize the far-reaching unconstitutional effects of the challenged policy by now-abandoned multiple challenges to the interaction of PFC denied as routine foot care with other statutes. Further confusion engendered by unfamiliar medical facts led the appellate court to ignore my authority of this court's decisions in: Memorial Hospital v. Maricopa County, 415 U.S. 250 (1974)--finding unconstitutional invidious discrimination (415 U.S. at 263,266) in state's indigent health program policy of denying timely funding for care rendered to prevent possible irrevocable loss of health but not that rendered after threat of loss became imminent, over state's objections that policy was justified by cost-saving and convenience; and Sosna v. Iowa, 419 U.S. 393,406

(1975)--holding penalty in Maricopa County, supra, resulted because claimant "irretreviably foreclosed from obtaining some part of what she sought" (here, patients' only reasons for Medicare enrollment, protection of health and economic security, are completely, irrevocably denied); and Cleburne v. Cleburne Living Center, 473 U.S. 432 (1985)--finding Equal Protection violation in claim by provider of joint federal-state funded residence for mentally retarded, on behalf of self and 13 potential residents (my patients), that city's restrictive zoning policy requiring "use permit" only for such residences with 7 or more members (here, PFC) meeting all applicable federal-state regulations (all Medicare reimbursability criteria are satisfied by my PFC), but not for other types of group residences with more members

(here, remedial care) based on city's unsupportable negative attitudes and fear of community harm (here, Medicare's fear that patients might receive reimbursement for service not essential to prevent loss of limb or life), as applied was not rationally related to legitimate governmental aims of protecting either the community or the mentally retarded.

The courts below, despite recognizing my claimed injury of lost income from PFC not performed (Appendix, pp. 6,14), wrongly denied my standing to argue that it results from my patients' inability to afford to purchase it because of Medicare's discriminatory PFC payment policy. I can't afford to perform PFC gratis. They can't obtain PFC or its medicare reimbursement unless I perform it. Thus, their rights will continue to be adversely affected by the challenged

policy unless I prevail. Similarly, if they can't afford PFC, they certainly can't afford to hire an attorney to litigate for the small amounts at issue here. If they could, time always would moot their similar claims before completion of litigation. My citation was ignored to the exact parallels of this court's decision in Craig v. Boren, 429 U.S. 190, 194-195 (1976)--in which an Equal Protection violation was found in law invidiously prohibiting vendor from selling to only one of two similar classes of buyers (as does 42 U.S.C. 1395u(1) under the challenged policy), and vendor was accorded standing to vindicate concomitant, mutually interdependent rights of buyer because denial of vendor's standing, where time moots buyer's claims (buyer/Medicare patient's similar claims mooted by amputation, death, or rapid

conversion of need for PFC reimbursement to need for already well-covered remedial care), and where continuing adverse effect on buyer's rights results from denial of vendor's standing, effect of such denial is "**impermissibly** to foster repetitive and time consuming litigation under guise of caution and prudence."

REASONS FOR GRANTING THIS WRIT

This discrimination may deprive thousands of the elderly of health, and thereby liberty, even though their only crime is old age and disease. If justice includes compassion, this court should rectify their plight.

CONCLUSION

For the foregoing reasons, this writ should be granted.

Respectfully submitted,

(Date) Duane L. Isaacs, D.P.M.
Petitioner Pro Se